

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: CHANDRASEKAR, Baskaran et al.
Serial No.: Not Yet Assigned
Filed: 18 March 2002
Title: LOCAL DELIVERY OF 17-BETA ESTRADIOL FOR PREVENTING VASCULAR
INTIMA HYPERPLASIA AND FOR IMPROVING VASCULAR ENDOTHELIUM
FUNCTION AFTER VASCULAR INJURY
Docket: 410718.90395

INFORMATION DISCLOSURE STATEMENT

- ☒ 1. Pursuant to 37 CFR 1.97(b) [within 3 mos. of filing or prior to 1st Office Action]
☐ 2. Certification Pursuant to 37 CFR 1.97(c) [before Final Office Action or Allowance]
☐ 3. Fee Payment Pursuant to 37 CFR 1.97(c) before Final Office Action or Allowance]
☐ 4. Petition, Certification & Petition Fee Payment Pursuant to 37 CFR 1.97(d) [before issue fee payment]

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

The following are submitted in the above-identified application in compliance with 37 CFR 1.97 & 1.98:

☒ 5. A list of documents on form PTO-1449, together with copies of each identified document and a translation or a concise explanation of each non-English language document is enclosed herewith. (These are the references cited in the PCT International Search Report.)

This paper is submitted in accordance with:

- ☒ 6. 37 CFR 1.97(b): [within 3 mos. of filing or prior to 1st Office Action]
☐ 7. 37 CFR 1.97(c): [before Final Office Action or Allowance, whichever is earlier]; and
☐ 8. The required certification made in item 11 below; or
☐ 9. The \$230.00 fee specified in 37 CFR \$1.17(p) for submission of this Information Disclosure Statement is authorized in item 14 below.

☐ 10. 37 CFR §1.97(d): [before issue fee payment]; and

(a) This is a petition for consideration of the subject Information Disclosure Statement. The petition fee (\$130.00) required by 37 CFR 1.17(i)(1) is authorized in item 14 below. (Direct this letter to: "Attn.: PETITIONS EXAMINER" and if applicable, include batch locator information: e.g. "Allowed Files, Batch _____, Date of Allowance _____"), and

(b) The required Certification is stated in item 11 below.

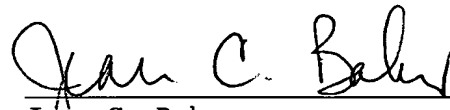
☐ 11. Certification

☐ 12. Each item of information contained in this Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement; or

☐ 13. No item of information contained in this Statement was cited in a communication from a foreign patent office in a counterpart foreign application, or to the knowledge of the person signing this document after making reasonable inquiry, was known to any individual designated in 37 CFR 1.56(c) more than three (3) months prior to the filing of this Statement.

☒ 14. Please charge all applicable fees associated with the submittal of this Information Disclosure Statement to Deposit Account No. 17-0055. An original and two (2) copies of this document are enclosed.

Respectfully submitted,



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JC10 Rec'd PCT/PTO 1 8 MAR 2002
Sheet 1 of 2

Express Mail No. EV077493871US

Form PTO-1449 (Rev. 2-88)				U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 410718.90395		SERIAL NO. UNASSIGNED	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT						APPLICANT CHANDRASEKAR, Baskaran et al.			
<i>(Use several sheets if necessary)</i>						FILING DATE 18 March 2002		GROUP	

U.S. PATENT DOCUMENTS							
* EXAMINER'S INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	1	5,376,652	12/27/94	Norman	514	177	
	2	5,866,561	2/2/99	Ungs	514	182	

FOREIGN PATENT DOCUMENTS								
DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION			
					YES	NO		
3	98/56312	12/17/98	WO					
4	00/12147	3/9/00	WO					
5	00/10552	3/2/00	WO					

OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>	
6	YOON YOUNG-SUP ET AL: "Local intraluminal infusion of oestradiol containing liposome in rat cartoid balloon injury model." EUROPEAN HEART JOURNAL, vol. 19, no. ABST. SUPPL. , August 1998 (1998-08), page 616; XP001014473; XXth Congress of the European Society of Cardiology; Vienna, Austria; August 22-26, 1998; ISSN: 0195-668X
7	ZHANG Y-Q ET AL: "EFFECTS OF GENDER AND ESTRADIOL TREATMENT ON FOCAL BRAIN ISCHEMIA", BRAIN RESEARCH, AMSTERDAM, NL, vol. 784, no. ½, 16 Feb 1998 (1998-02-16), pages 321-324, XP000884355; ISSN: 0006-8993
8	KAUFFMAN RAYMOND F ET AL: "Comparative effects of local vs. systemic administration of estrogen upon vascular responses to balloon injury." CIRCULATION, vol. 92, no. 8 SUPPL., 1995, page 1628; XP001014766; 68 th Scientific Session of the American Heart Association; Anaheim, CA; USA; November 13-16, 1995; ISSN: 0009-7322

EXAMINER	DATE CONSIDERED
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* EXAMINER: Initial if a citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Express Mail No. EV077493871US

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FOREIGN PATENT DOCUMENTS							
DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION		
					YES	NO	

OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>	
9	DATABASE BIOSIS Online! BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; May 1999 (199-05); PERROT-APPLANAT M: "Qestradiol and proliferation of vascular cells." Database accession no. PREV200000507148; XP002177140; abstract & THERAPIE (LONDON), vol. 54, no. 3, May 1999 (1999-05), pages 333-337, ISSN: 0040-5957
10	DATABASE BIOSIS Online! BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; 1995 MIKKOLA TOMI ET AL: "17-beta-estradiol stimulates prostacyclin, but not endothelin-1, production in human vascular endothelial cells." Database accession no. PREV199598355996; XP002177141; abstract & JOURNAL OF CLINICAL ENDOCRINOLOGY & METABOLISM, vol. 80, no. 6, 1995, pages 1832-1836; ISSN: 0021-972X
11	DATABASE BIOSIS Online! BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; 1996 MIKKOLA TOMI ET AL: "Effect of physiological concentrations of estradiol on PGI-2 and NO in endothelial cells." Database accession no. PREV199799286811; XP002177142; abstract & MATURITAS, vol. 25, no. 2, 1996, pages 141-147; ISSN: 0378-5122
12	CHANDRASEKAR, BASKARAN, (1) ET AL: "Coronary artery endothelial protection following local delivery of 17-beta estradiol during balloon angioplasty: A potential new pharmacological approach to improve long-term outcome of angioplasty." JOURNAL OF AMERICAN COLLEGE OF CARDIOLOGY, (FEB., 2000) VOL. 35, NO. 2, SUPPL. A, PP. 58A, MEETING INFO.: 29 TH ANNUAL SCIENTIFIC SESSION OF THE AMERICAN COLLEGE OF CARDIOLOGY, ANAHEIM, CA, USA MARCH 12-15, 2000; XP001015229
13	SELZMAN, CRAIG H. ET AL: "Estrogen replacement inhibits intimal hyperplasia and the accumulation and effects of transforming growth factor .beta.1", J. SURG. RES. (1998), 80(2), 380-385; XP001014759
14	KEANY J. F. ET AL: "17BETA-ESTRADIOL PRESERVES ENDOTHELIAL VASODILATOR FUNCTION AND LIMITS LOW-DENSITY LIPOPROTEIN OXIDATION IN HYPERCHOLESTEROLEMIC SWINE" CIRCULATION, AMERICAN HEART ASSOCIATE, DALLAS, TX, US., vol 89, no. 5, May 1994 (1994-05), pages 2251-2259; XP001014735; ISSN: 0009-7322
15	DATABASE BIOSIS Online! BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; 1996; KUBLIK HEIKE ET AL: "Nasal absorption of 17-beta-estradiol from different cyclodextrin inclusion formulations in sheep." Database accession no. Prev199799383935; xp002177143; abstract & EUROPEAN JOURNAL OF PHARMACEUTICS AND BIOPHARMACEUTICS, vol. 42, no. 6, 1996, pages 320-324; ISSN: 0939-6411

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